K040947

AUG 27 2004

510(k) SUMMARY

SPONSOR NAME: Zimmer
9900 Spectrum Drive
Austin, TX 78717

510(k) CONTACT: Audrey Swearingen
Phone: (512) 432-9255
Audrey.Swearingen@Zimmer.com

TRADE NAME: Durasul® Bipolar

COMMON NAME: Hemi-Hip

CLASSIFICATION: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented or Uncemented Prosthesis (87 KWY) are Class II per 21 CFR §888.3390.

PREDICATE DEVICES:

- Centerpulse Orthopedics, Inc. Bipolar (K873815) and
- Exactech's AcuMatch L-Series Bipolar (K013211).

DEVICE DESCRIPTION:

The Durasul Bipolar consists of a polyethylene insert/liner and an outer CoCr shell. *In vivo*, the CoCr shell articulates directly with well-preserved articular cartilage while the Durasul insert articulates directly with a 22 or 26mm femoral head. The Durasul Bipolar components are available in a variety of sizes to allow the surgeon to replicate the natural anatomy of the hip joint as closely as possible when performing a hip hemi-arthroplasty.

INTENDED USE:

The Durasul Bipolar is intended for non-cemented use in a hip hemi-arthroplasty in which it assumes the function of the natural femoral head in conjunction with a prosthetic femoral head component. Specific diagnostic indications for use of a bipolar include displaced femoral neck fractures, avascular necrosis of the femoral head, and non-union of femoral neck fractures.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests, design comparisons, and functional analyses conducted on the Durasul Bipolar demonstrate that this device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Ms. Audrey Swearingen
Manager, Regulatory Affairs
Zimmer Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K040947
Trade/Device Name: Durasul® Bipolar
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: August 6, 2004
Received: August 9, 2004

Dear Ms. Swearingen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

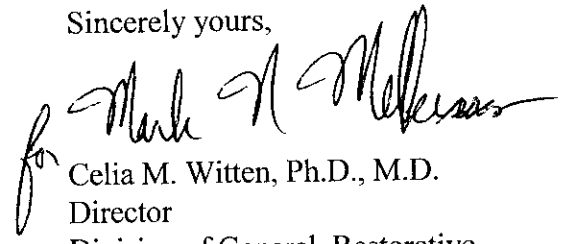
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040947

Device Name: Durasul® Bipolar

Indications for Use:

The Durasul Bipolar is intended for non-cemented use in a hip hemi-arthroplasty in which it assumes the function of the natural femoral head in conjunction with a prosthetic femoral head component. Specific diagnostic indications for use of a bipolar include displaced femoral neck fractures, avascular necrosis of the femoral head, and non-union of femoral neck fractures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040947